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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,449	09/22/2003	Alfred Weber	SCH-1743 CI	6844
23599	7590	11/15/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/665,449

Applicant(s)

WEBER ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 54-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54,55 and 63-70 is/are rejected.
- 7) ☒ Claim(s) 56-62 and 71-76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/509,608.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 54-63 and 68-76 in the response to restriction requirement file September 1, 2006 is acknowledged. The traversal is on the ground(s) that the claims in the instant application involve related subject matter, for example, a method of producing ergosterol and its intermediate products, as recited in the claims. A search of all the claims would comprise overlapping subject matter, and it would not be an undue burden on the Examiner to carry out a search. The response has been considered, and the arguments are found persuasive. Thus, the restriction requirement has been withdrawn, and claims 54-76 are examined.

### ***Objections to the Specification***

2. The specification is objected for lacking an adequately descriptive Abstract. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. In the instant case, the Abstract does not mention the types of enzymes used; it lacks any specific description of the disclosed subject matter. The Examiner suggests the inclusion of the enzyme names, in full and their abbreviations, for completeness.

### ***Claim Objections***

3. Claims 56-62 and 71-76 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 56-62 and 71-76 have not been further treated on the merits.

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4. Claim 54 is objected to because the claim recites the terms “ Process for the production...”, “v) the gene of squalene epoxidase (ERG1)”, and “b) first plasmids are digested, into which in each case one of the genes of the genes.....inserted”. Use of the terms “ A process for the production...”, “iv) the gene of squalene epoxidase (ERG1)”, and “b) first plasmids are digested, into which in each case one ~~of the genes~~ of the genes.....inserted” are suggested.

5. Claim 55 is objected to because the claim recites the term “ Process according to claim 1”. Use of “The process according to claim 1” is suggested. See also claims 63, 64, 68 and 70 regarding adding the article “the”, “a” or “an” to the claim.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 65-67 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 54, 55 and 63-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 54 and 55 are indefinite because of the use of the term "its intermediate products". The term cited renders the claim indefinite, it is not clear what are the metes and bounds for the intermediate products of ergosterol since the intermediate products are not identified, nor the reactions are specified. Claim 55 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

9. Claims 54, 55 and 63-70 are indefinite because the claim recites the terms "the gene of the HMG-Co-reductase (t-HMG)", "the gene of the squalene synthetase (ERG9)", "the gene of the acyl-CoA; sterol-acyltransferase (SAT1)", "the gene of squalene epoxidase (ERG1)", "the t-HMG gene", "the SAT1 gene", or "the ERG9 gene", it is not clear what specific gene the term refers to, e.g., does "the t-HMG gene" refers to the t-HMG gene from *S. cerevisiae* or from other microorganisms?

10. Claims 55 and 65-67 are indefinite because the claims depend from a cancelled claim, claim 1 or claim 11.

11. Claim 63 recites the limitation " the process under a-i)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

12. Claims 65-67 recites the use of the plasmid pADL-SAT1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 63-67 are rejected under 35 U.S.C. § 112, first paragraph, enabling the deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To practice the instant methods or to make the claimed products, one of skill in the art is required to use YE<sub>p</sub>H<sub>2</sub>, YD<sub>p</sub>UHK<sub>3</sub>, and pADL-SAT1 plasmids or AH22 cells. The instant specification contains no deposit information concerning these plasmids and/or cells. To enable the instant claims by enabling the deposit of YE<sub>p</sub>H<sub>2</sub>, YD<sub>p</sub>UHK<sub>3</sub>, and pADL-SAT1 plasmids, the following items are required: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and full address of the depository (37 C.F.R. § 1.801 - 1.809), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative. An alternative to the deposit of the exact plasmids is the deposit of all precursor plasmids required to produce the claimed plasmids as described in the specification.

***Conclusions***

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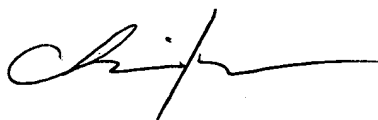
14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

November 11, 2006